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EXAMINER	
SOREY, ROBERT A	

ART UNIT	PAPER NUMBER
3626	

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12/30/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/560,963	HEBBLEWHITE ET AL.	
	Examiner	Art Unit	
	ROBERT SOREY	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 October 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. As per the submission to the Office filed on 10/21/2010, the following represents the current status of the claims: Claims 1-20 were cancelled; and claims 21-35 were added. Claims 21-35 are presented for examination.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. **Claims 21-27** is/are rejected under 35 U.S.C. 101 because, based upon consideration of all of the relevant factors with respect to the claim as a whole, the claim(s) is/are held to claim an abstract idea, and is/are therefore rejected as ineligible subject matter under 35 U.S.C. 101 (see: Bilski v. Kappos, 95 USPQ2d 1001 (U.S. 2010)). In particular, the rationale for finding that claim(s) is/are directed toward non-statutory subject matter include among others:

- No recitation of a machine or transformation, either express or inherent; and/or
- Insufficient recitation of a machine or transformation:
    - Involvement of machine, or transformation, with the steps is merely nominally, insignificantly, or tangentially related to the performance of the steps, e.g., data gathering, or merely recites a field in which the method is intended to be applied.
    - Machine is generically recited such that it covers any machine capable of performing the claimed step(s).

- Machine is merely an object on which the method operates.
- Transformation involves only a change in position or location of article.
- Article is merely a general concept.

4. An example of a method claim that would not qualify as a statutory process would be a claim that recited purely mental steps. Thus, to qualify as a § 101 statutory process, the claim should positively recite the other statutory class (such as, for example, a particular **machine**) to which it is tied. This can be done, for example, by identifying the apparatus that accomplishes the method steps, by positively reciting the subject matter that is being transformed, or by identifying the material that is being changed to a different state.

5. Applicant's method steps in **claims 21-27** fail the first prong of the new Federal Circuit decision since they are not tied to another statutory class and can be preformed without the use of a particular apparatus. Furthermore, the method steps fail to transform underlying subject matter to a different state or thing. For example, claim 1 teaches obtaining and storing data and analyzing the data, but in no way is it clear as to how this is accomplished (such as, accomplished by a particular **machine**).

6. Dependent claim(s) 2-27 when analyzed as a whole are held to be patent ineligible under 35 U.S.C. 101 because the additional recited limitation(s) similarly fail(s) to establish that the claim(s) is/are not directed to an abstract idea.

7. It is recommended that Applicant simply add any structural language from the specification as necessary to complete a statutorily compliant method having Applicant's desired capabilities.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. **Claims 21-35** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. As per claim 21, Applicant claims "obtaining and storing (1) data representative of a patient's treatment over a selected time period...and (2) results regarding treatment of a plurality of patients...analyzing said data in relation to said results" but it is unclear as to which data is being analyzed. Applicant claims that "said data" is being analyzed in relation to "said results" but both patient treatment and results were stored and collected. Which obtained and stored data is being analyzed? Claim 28 is rejected for similar reasons.

11. As per claim 21, in part (2) concerning the obtaining and storing of results data, Applicant claims that the obtained and stored data "include[s] a determination of improvement together with BMI and one or more of AHI, AI, usage, and CPAP titration", but it is unclear as to if this is merely obtained and stored data or if this is calculated data. Where did this data come from and how was it calculated? Was it merely obtained and stored or did Applicant's invention calculate this data? Claim 28 is rejected for similar reasons.

12. As per claim 21, Applicant claims (A) "analyzing said data in relation to said results in order to facilitate a comparative determination of the relative effectiveness of

SDB management of said patient" and (B) "compare trends in BMI and one or more of AHI, AI, usage, and CPAP titration data among said patient treatment data to those of said representative treatment results". Are (A) and (B) two different calculations or the same calculation? Could there be an analysis that would satisfy (A) but not (B)? Claim 28 is rejected for similar reasons.

13. As per claim 21, Applicant claims "a determination of improvement" and "a comparative determination of the relative effectiveness" but it is unclear as to if these are the same calculations or if these are different calculations. What is the difference between "a determination of improvement" and "a comparative determination of the relative effectiveness"? Why does Applicant need to calculate "a comparative determination of the relative effectiveness" when "a determination of improvement" was obtained and stored in the previous step? Claim 28 is rejected for similar reasons.

14. As per claim 21, Applicant claims analyzing the data and, perhaps, comparing the data, but it is unclear as to how this data is compared so as to "determine the relative effectiveness of SDB management of said patient". How does comparing data result in a determination of relative effectiveness of SDB management? Applicant's analysis, comparison, and determination of effectiveness are unclear. Additionally, it does not appear that the determination step is a part of the claim as it is currently directed toward the intended use of the claimed invention, and the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior

art. If the prior art structure is capable of performing the intended use, then it meets the claim. Claim 28 is rejected for similar reasons.

15. As per claim 22, Applicant claims "wherein the selected time period is adjustable" but it is unclear as to how one can adjust the time period when the data associated with the time period is merely obtained and stored. How does one adjust the time period of obtained and stored data? Claim 29 is rejected for similar reasons.

16. As per claim 23, Applicant claims the terms "normal, overweight, obese, and extremely obese" which are relative terms which render the claim indefinite. The terms "normal, overweight, obese, and extremely obese" are not defined by the claim. Claim 31 is rejected for similar reasons.

17. As per claims 24-27 and 32-35, Applicant claims, for example, a normal BMI range of 19-24 and an overweight BMI rage of 25-29, but it is unclear as to what occurs to a person with a BMI of 24.5, for example. How does Applicant's invention characterize a person with BMI of 24.5?

18. As per claim 28, Applicant claims "a storage mechanism for obtaining and storing", but it is unclear as to what this mechanism and its functionality include. Is the storage mechanism actually something mechanical or perhaps a computer? Is the storage device connected to or in any way a part of the computing device of the subsequent limitation?

19. Claim 30 is rejected for similar reasons.

Claim Rejections - 35 USC § 103

20. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

21. **Claims 21, 22, and 28-30** are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication 2003/0208465 to Yurko in view of U.S. Patent 6,811,538 to Westbrook.

22. As per claim 21, a method for determining the effectiveness of sleep disordered breathing ("SDB") management of a patient using a computer comprising the steps of:

--*obtaining and storing* (Fig. 1)(see: Yurko, paragraph 32-34 and 43-49, is met by data stored in a database on a computer) *(1) data representative of a patient's treatment over a selected time period* (Fig. 8A)(see: Yurko, paragraph 28, is met by device usage dates; paragraph 34 and 68, is met by start date and end data), *said data including body mass index ("BMI")* (Fig. 10)(see: Yurko, paragraph 29 and 74, is met by weight and body mass index (BMI)) *and one or more of apnea hypopnea index ("AHI"), apnea index ("At"), usage and continuous positive airway pressure ("CPAP") titration* (Fig. 23A-23E)(see: Yurko, paragraph 29, 63, 69, 74, and 111-112, is met by CPAP daily usage and compliance), *and*

Yurko teaches using the present invention in connection with the therapeutic treatment in monitoring of sleeping disorders, the patient-specific data may correspond to body mass index (see: Yurko, paragraph 29), and the system provides summaries of

the data collected for patients in table, chart, and statistical form using a CPAP system (see: Yurko, at least paragraph 111 and 112); however, Yurko fails to specifically teach:

said BMI data being used to characterize said patient;

--(2) results regarding treatment of a plurality of patients for obstructive sleep apnea, including a determination of improvement together with BMI and one or more of AHI, AI, usage, and CPAP titration, and

--analyzing said data in relation to said results in order to facilitate a comparative determination of the relative effectiveness of SDB management of said patient, and to compare trends in BMI and one or more of AHI, AI, usage, and CPAP titration data among said patient treatment data to those of said representative treatment results so as to determine the relative effectiveness of SDB management of said patient.

Westbrook, however, teaches characterizing a patient's BMI as being greater or less than a specific level (see: Westbrook, Table 3), a relationship between input data concerning a patient's BMI or body mass index (see: Westbrook, column 21, line 60 through column 22, line 8), and input data from a physiological monitoring/therapeutic device such as a CPAP device (see: Westbrook, column 25, lines 37-57) to produce logic-based reports that present an analysis of a session(s)-over-time based on the inputted data (see Westbrook, column 23, line 1 through column 24, line 33).

Furthermore, Westbrook teaches that the analysis of such data is based on comparing the data against a sleep apnea database which contains physiological sleep data from at least one person who is classified as suffering from sleep apnea and from at least one person who is not suffering from sleep apnea (the "control") (see:

Westbrook, column 8, line 37 through column 9, line 7), the reports being designed to meet the needs of both consumers and physicians (see: Westbrook, column 24, lines 28-32).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Yurko and Westbrook. The well known elements described are merely a combination of old elements, and in the combination, each element merely would have performed the same function as it did separately, and one of ordinary skill in the art would have recognized that the results of the combination were predictable.

23. As per claim 22, Yurko and Westbrook teach the invention as claimed, see discussion of claim 21, and further teach:

--*wherein the selected time period is adjustable* (Fig. 8A; and Fig. 23B)(see: Yurko, paragraph 28, is met by device usage dates; paragraph 34 and 68, is met by start date and end data being adjustable; and paragraph 112, is met by exclusion days).

24. As per claim 28, Yurko teaches an apparatus for determining the effectiveness of sleep disordered breathing ("SDB") management of a single patient comprising:

--*a storage mechanism for obtaining and storing* (Fig. 1)(see: Yurko, paragraph 32-34 and 43-49, is met by data stored in a database on a computer) *(1) data representative of said patient's characteristics and treatment of SDB over a selected time period* (Fig. 8A)(see: Yurko, paragraph 28, is met by device usage dates; paragraph 34 and 68, is met by start date and end data), *said data including said patient's body mass index ("BMI")* (Fig. 10)(see: Yurko, paragraph 29 and 74, is met by

weight and body mass index (BMI)) *and one or more of apnea hypopnea index ("AHI"), apnea index ("AI"),usage and CPAP titration, and (2) results regarding a plurality of patients' treatment of obstructive sleep apnea including a determination of improvement together with BMI and one or more of AHI, AI, usage, and CPAP titration* (Fig. 23A-23E)(see: Yurko, paragraph 29, 63, 69, 74, and 111-112, is met by CPAP daily usage and compliance);

--*a display coupled to said computer for displaying results of said analysis* (Fig. 1; and Fig. 23A-23E)(see: Yurko, paragraph 43-49, is met by computer interface for data presentation; and paragraph 111-112, is met by reports).

Yurko teaches using the present invention in connection with the therapeutic treatment in monitoring of sleeping disorders, the patient-specific data may correspond to body mass index (see: Yurko, paragraph 29), and the system provides summaries of the data collected for patients in table, chart, and statistical form using a CPAP system (see: Yurko, at least paragraph 111 and 112); however, Yurko fails to specifically teach:

said BMI data being used to characterize said patient;

--*a flow generator for generating controlled continuous positive airway pressure ("CPAP") titrated airflow to a patient;*

--*a computer programmed to analyze said data regarding said patient's treatment relative to said results regarding a plurality of patients' treatment in order to facilitate a comparative determination of the relative effectiveness of SDB management of said patient; and*

Westbrook, however, teaches characterizing a patient's BMI as being greater or less than a specific level (see: Westbrook, Table 3), a relationship between input data concerning a patient's BMI or body mass index (see: Westbrook, column 21, line 60 through column 22, line 8), and input data from a physiological monitoring/therapeutic device such as a CPAP device (see: Westbrook, column 25, lines 37-57) to produce logic-based reports that present an analysis of a session(s)-over-time based on the inputted data (see Westbrook, column 23, line 1 through column 24, line 33).

Furthermore, Westbrook teaches that the analysis of such data is based on comparing the data against a sleep apnea database which contains physiological sleep data from at least one person who is classified as suffering from sleep apnea and from at least one person who is not suffering from sleep apnea (the "control") (see: Westbrook, column 8, line 37 through column 9, line 7), the reports being designed to meet the needs of both consumers and physicians (see: Westbrook, column 24, lines 28-32).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Yurko and Westbrook. The well known elements described are merely a combination of old elements, and in the combination, each element merely would have performed the same function as it did separately, and one of ordinary skill in the art would have recognized that the results of the combination were predictable.

25. As per claim 29, Yurko and Westbrook teach the invention as claimed, see discussion of claim 28, and further teach:

--*wherein the selected time period is adjustable* (Fig. 8A; and Fig. 23B)(see: Yurko, paragraph 28, is met by device usage dates; paragraph 34 and 68, is met by start date and end data being adjustable; and paragraph 112, is met by exclusion days).

26. As per claim 30, Yurko and Westbrook teach the invention as claimed, see discussion of claim 28, and further teach:

--*wherein the patient characterization is displayed as a label on a single screen of said display.*

Yurko teaches a computer interface for data presentation and reports (Fig. 1; and Fig. 23A-23E)(see: Yurko, paragraph 43-49; and paragraph 111-112), and it would have been obvious to one or ordinary skill in the art at the time the invention was made to display the patient characterizations as taught by Trends (see: Trends, page 1585, under the heading of "Data collection") on a single screen with the motivation of streamlining data presentation so as to reduce or eliminate the amount of time it takes to click-through and/or load said information on separate screens.

27. **Claims 23-27 and 31-35** are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication 2003/0208465 to Yurko in view of U.S. Patent 6,811,538 to Westbrook further in view of Trends (Cynthia L Leibson, David F Williamson, L Joseph Melton III, Pasquale J Palumbo, et al. "Temporal Trends in BMI Among Adults With Diabetes". Diabetes Care. Alexandria: Sep 2001. Vol. 24, Iss. 9; p. 1584).

28. As per claim 23, Yurko and Westbrook teach the invention as claimed, see discussion of claim 21, but fail to specifically teach:

--*wherein patient characterizations include normal, overweight, obese, and extremely obese.*

However, Trends teaches BMI characterizations of normal, overweight, obese, and extremely obese (see: Trends, page 1585, under the heading of "Data collection").

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Yurko, Westbrook, and Trends. The well known elements described are merely a combination of old elements, and in the combination, each element merely would have performed the same function as it did separately, and one of ordinary skill in the art would have recognized that the results of the combination were predictable.

29. As per claim 24, Yurko, Westbrook, and Trends teach the invention as claimed, see discussion of claim 23, and further teach:

--*wherein a patient characterization of normal represents a BMI range of 19-24* (see: Trends, page 1585, under the heading of "Data collection", is met by a normal BMI range of 18.5-24.9)

30. As per claim 25, Yurko, Westbrook, and Trends teach the invention as claimed, see discussion of claim 23, and further teach:

--*wherein a patient characterization of overweight represents a BMI range of 25-29* (see: Trends, page 1585, under the heading of "Data collection", is met by an overweight BMI range of 25.0-29.9).

31. As per claim 26, Yurko, Westbrook, and Trends teach the invention as claimed, see discussion of claim 23, and further teach:

--*wherein a patient characterization of obese represents a BMI range of 30-39* (see: Trends, page 1585, under the heading of "Data collection", is met by an obese BMI range of 30.0-39.9).

32. As per claim 27, Yurko, Westbrook, and Trends teach the invention as claimed, see discussion of claim 23, and further teach:

--*further including a patient characterization of extremely obese representing a BMI range of 40-54* (see: Trends, page 1585, under the heading of "Data collection", is met by an extremely obese BMI range of 40 and over).

33. As per claim 31, Yurko and Westbrook teach the invention as claimed, see discussion of claim 28, but fail to specifically teach:

--*wherein patient characterizations include normal, overweight, obese, and extremely obese.*

However, Trends teaches BMI characterizations of normal, overweight, obese, and extremely obese (see: Trends, page 1585, under the heading of "Data collection").

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Yurko, Westbrook, and Trends. The well known elements described are merely a combination of old elements, and in the combination, each element merely would have performed the same function as it did separately, and one of ordinary skill in the art would have recognized that the results of the combination were predictable.

34. As per claim 32, Yurko, Westbrook, and Trends teach the invention as claimed, see discussion of claim 31, and further teach:

--*wherein a patient characterization of normal represents a BMI range of 19-24* (see: Trends, page 1585, under the heading of "Data collection", is met by a normal BMI range of 18.5-24.9).

35. As per claim 33, Yurko, Westbrook, and Trends teach the invention as claimed, see discussion of claim 31, and further teach:

--*wherein a patient characterization of overweight represents a BMI range of 25-29* (see: Trends, page 1585, under the heading of "Data collection", is met by an overweight BMI range of 25.0-29.9).

36. As per claim 34, Yurko, Westbrook, and Trends teach the invention as claimed, see discussion of claim 31, and further teach:

--*wherein a patient characterization of obese represents a BMI range of 30-39* (see: Trends, page 1585, under the heading of "Data collection", is met by an obese BMI range of 30.0-39.9).

37. As per claim 35, Yurko, Westbrook, and Trends teach the invention as claimed, see discussion of claim 31, and further teach:

--*further including a patient characterization of extremely obese representing a BMI range of 40-54* (see: Trends, page 1585, under the heading of "Data collection", is met by an extremely obese BMI range of 40 and over).

Response to Arguments

38. Applicant's arguments from the response filed on 10/21/2010 have been fully considered and will be addressed below in the order in which they appeared.

39. In the remarks, Applicant argues in substance that (1) the 35 U.S.C. 112, second paragraph, rejections should be withdrawn because the term "ascertaining relationships and trends" has been replaced.

The rejected claim and the rejected claim language have been canceled; therefore, the rejection has been withdrawn.

40. In the remarks, Applicant argues in substance that (2) "Yurko does not disclose or suggest any display or anything related to BMI".

The Examiner respectfully disagrees. Applicant's arguments are not persuasive. Yurko teaches that in connection with the therapeutic treatment in monitoring of sleeping disorders, the patient-specific data may correspond to a body mass index, and further teaches obtaining patient information via a patient medical history entry form screen wherein the information obtained includes the patient's BMI (Fig. 10)(see: Yurko, paragraph 29 and 74).

41. In the remarks, Applicant argues in substance that (3) "Westbrook is relied upon for teaching a relationship between input data concerning BMI and input data from a physiological monitoring or therapeutic device such as CPAP as well as teaching that the analysis of such data is based on comparing the data against a sleep apnea database. However, the particular data obtained (including AI, and AHI) and comparisons made in the present invention are not disclosed or suggested in Westbrook. Also, the Examiner indicates that Westbrook teaches a comparison between data related to a patient and data related to at least one other patient. However, Westbrook merely teaches analysis using data collected through a

questionnaire, not data of actual events, and does not teach analysis of directly-collected physiological data or analysis of the particular data collected in the present invention."

The Examiner respectfully disagrees. Applicant's arguments are not persuasive.

Applicant argues that particular data including AI and AHI are not taught by Westbrook. The Examiner has not thoroughly searched Westbrook for AI and AHI data and cannot comment as to whether Westbrook teaches the particular data because the claim limitation in question is broadly written and does not require those particular data types argued. Specifically, Applicant claims obtaining and storing data wherein the data includes "*one or more of apnea hypopnea index ("AHI"), apnea index ("AI"), usage and continuous positive airway pressure ("CPAP") titration*". Westbrook, as cited, teaches obtaining and storing CPAP titration data (Fig. 23A-23E)(see: Yurko, paragraph 29, 63, 69, 74, and 111-112, is met by CPAP daily usage and compliance), which is all that is required by Applicant's limitation due to the "one or more of" language.

As per the assertion that "Westbrook merely teaches analysis using data collected through a questionnaire, not data of actual events", Westbrook was not relied upon for the obtaining and storing of data, which was taught by Yurko. Applicant argues against Westbrook individually and one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

As per the assertion that Westbrook "does not teach analysis of directly-collected physiological data or analysis of the particular data collected in the present invention", Westbrook teaches that data from a physiological monitoring/therapeutic device such as a CPAP device (see: Westbrook, column 25, lines 37-57) is used to produce logic-based reports that present an analysis of a session(s)-over-time based on the inputted data (see Westbrook, column 23, line 1 through column 24, line 33). Furthermore, Westbrook teaches that the analysis of such data is based on comparing the data against a sleep apnea database which contains physiological sleep data from at least one person who is classified as suffering from sleep apnea and from at least one person who is not suffering from sleep apnea (the "control") (see: Westbrook, column 8, line 37 through column 9, line 7), the reports being designed to meet the needs of both consumers and physicians (see: Westbrook, column 24, lines 28-32).

42. Applicant's remaining arguments have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

43. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

44. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

45. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT SOREY whose telephone number is (571) 270-3606. The examiner can normally be reached on Monday through Friday, 8:30AM to 5:00PM (EST).

46. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Morgan can be reached on (571) 272-6773. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

47. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. S./
Examiner, Art Unit 3626

/Dilek B Cobanoglu/
Primary Examiner, Art Unit 3626